§ 884.5360 Contraceptive intrauterine device (IUD) and introducer.

(a) *Identification.* A contraceptive intrauterine device (IUD) is a device used to prevent pregnancy. The device is placed high in the uterine fundus with a string extending from the device through the cervical os into the vagina. This generic type of device includes the introducer, but does not include contraceptive IUD's that function by drug activity, which are subject to the new drug provisions of the Federal Food, Drug, and Cosmetic Act (see § 310.502).

(b) *Classification.* Class III (premarket approval).

(c) *Labeling.* Labeling requirements for contraceptive IUD's are set forth in § 801.427.

(d) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before August 4, 1986, for any IUD and introducer that was in commercial distribution before May 28, 1976, or that has on or before August 4, 1986, been found to be substantially equivalent to an IUD and introducer that was in commercial distribution before May 28, 1976. Any other IUD and introducer shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684–12720, Feb. 26, 1980, as amended at 51 FR 16649, May 5, 1986]

§ 884.5380 Contraceptive tubal occlusion device (TOD) and introducer.

(a) *Identification.* A contraceptive tubal occlusion device (TOD) and introducer is a device designed to close a fallopian tube with a mechanical structure, e.g., a band or clip on the outside of the fallopian tube or a plug or valve on the inside. The devices are used to prevent pregnancy.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 30, 1987, for any TOD and introducer that was in commercial distribution before May 28, 1976, or that has on or before December 30, 1987, been found to be substantially equivalent to a TOD and introducer that was in commercial distribution before May 28, 1976. Any other TOD and introducer shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684–12720, Feb. 26, 1980, as amended at 52 FR 36883, Oct. 1, 1987]

§ 884.5390 Perineal heater.

(a) *Identification.* A perineal heater is a device designed to apply heat directly by contact, or indirectly from a radiant source, to the surface of the perineum (the area between the vulva and the anus) and is used to soothe or to help heal the perineum after an episiotomy (incision of the vulvar orifice for obstetrical purposes).

(b) *Classification.* Class II (performance standards).

§ 884.5400 Menstrual cup.

(a) *Identification.* A menstrual cup is a receptacle placed in the vagina to collect menstrual flow.

(b) *Classification.* Class II (performance standards).

§ 884.5425 Scented or scented deodorized menstrual pad.

(a) *Identification.* A scented or scented deodorized menstrual pad is a device that is a pad made of cellulosic or synthetic material which is used to absorb menstrual or other vaginal discharge. It has scent (i.e., fragrance materials) added for aesthetic purposes (scented menstrual pad) or for deodorizing purposes (scented deodorized menstrual pad). This generic type of device includes sterile scented menstrual pads used for medically indicated conditions, but does not include menstrual pads treated with added antimicrobial agents or other drugs.

(b) *Classification.* (1) Class I (general controls) for menstrual pads made of common cellulosic and synthetic material with an established safety profile. The devices subject to this paragraph (b)(1) are exempt from the premarket notification procedures in subpart E of

part 807 of this chapter, subject to the limitations in § 884.9. This exemption does not include the intralabial pads and reusable menstrual pads.

(2) Class II (special controls) for scented or scented deodorized menstrual pads made of materials not described in paragraph (b)(1).

[45 FR 12684–12720, Feb. 26, 1980, as amended at 45 FR 51185, Aug. 1, 1980; 61 FR 67714, Dec. 24, 1996; 66 FR 38809, July 25, 2001]

§ 884.5435 Unscented menstrual pad.

(a) *Identification.* An unscented menstrual pad is a device that is a pad made of cellulosic or synthetic material which is used to absorb menstrual or other vaginal discharge. This generic type of device includes sterile unscented menstrual pads used for medically indicated conditions, but does not include menstrual pads treated with scent (i.e., fragrance materials) or those with added antimicrobial agents or other drugs.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device is made of common cellulosic and synthetic material with an established safety profile. This exemption does not include the intralabial pads and reusable menstrual pads.

[45 FR 12684–12720, Feb. 26, 1980, as amended at 61 FR 67714, Dec. 24, 1996; 65 FR 2320, Jan. 14, 2000; 73 FR 34860, June 19, 2008]

§ 884.5460 Scented or scented deodorized menstrual tampon.

(a) *Identification.* A scented or scented deodorized menstrual tampon is a device that is a plug made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge. It has scent (i.e., fragrance materials) added for aesthetic purposes (scented menstrual tampon) or for deodorizing purposes (scented deodorized menstrual tampon). This generic type of device does not include menstrual tampons treated with added antimicrobial agents or other drugs.

(b) *Classification.* Class II (performance standards).

[45 FR 12684-12720, Feb. 26, 1980, as amended at 45 FR 51186, Aug. 1, 1980]

§ 884.5470 Unscented menstrual tampon.

(a) *Identification.* An unscented menstrual tampon is a device that is a plug made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge. This generic type of device does not include menstrual tampons treated with scent (i.e., fragrance materials) or those with added antimicrobial agents or other drugs.

(b) *Classification.* Class II (performance standards).

§ 884.5900 Therapeutic vaginal douche apparatus.

(a) *Identification.* A therapeutic vaginal douche apparatus is a device that is a bag or bottle with tubing and a nozzle. The apparatus does not include douche solutions. The apparatus is intended and labeled for use in the treatment of medical conditions except it is not for contraceptive use. After filling the therapeutic vaginal douche apparatus with a solution, the patient uses the device to direct a stream of solution into the vaginal cavity.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I if the device is operated by gravity feed. Devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9.

[45 FR 12684–12720, Feb. 26, 1980, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38809, July 25, 2001]

§ 884.5920 Vaginal insufflator.

(a) *Identification.* A vaginal insufflator is a device used to treat vaginitis by introducing medicated powder from a hand-held bulb into the vagina through an open speculum.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807